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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/234,208	01/20/1999	JONI KRISTIN DOHERTY	49321-1	6406

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

MAIL DATE	DELIVERY MODE
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04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action
Before the Filing of an Appeal Brief

Application No.

09/234,208

Applicant(s)

DOHERTY ET AL.

Examiner

Susan Ungar

Art Unit

1642

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 21 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

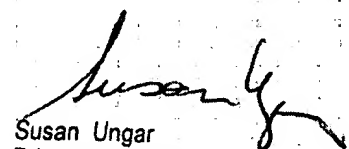
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: 27 and 28.
Claim(s) objected to: _____.
Claim(s) rejected: 1-3, 8-10, 18-20 and 28-30.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☒ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.


Susan Ungar
Primary Examiner
Art Unit: 1642

Continuation of 11, does NOT place the application in condition for allowance because: 1. Claims 1-3, 8-9, 18-20, 29-30 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the: paper mailed July 26, 2006, Section 4, pages 2-9. Applicant reiterates Examiner's rejection and cites case law drawn to Atlas Powder Co. v. E.I. DuPont de Nemours, In re Anderson, In re Marzocchi et al, In re Grimme, Keil and Schmitz, Smith v. Snow, and argues that there is no requirement for disclosure of every species within a genus. The argument Applicant has been considered but has not been found persuasive because (a) Applicant does not discuss the fact patterns of the cited case law, does not provide a nexus with the fact pattern of the instant invention and that of the cited cases or how the decisions in the case law are on point for the instantly claimed rejections.

Applicant points to the In re Wands and argues that the instant application meets the requirements of the Wands factors and reiterates previous arguments drawn to general techniques for isolating, expressing and testing polypeptides comprising all or part of the sequence of p68HER-2. The arguments were previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments that the claims are within the scope of what is taught in the specification. The argument was previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments that the level of skill is recognized to be high. The argument was previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments that a broad body of knowledge was available and known about HER-2 at the time the invention was made wherein truncated variants of HER-2 were known and analyzed for function. The argument was previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments that the teachings of the specification and working examples enable the claimed invention. The arguments were previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments drawn to the teachings of the working examples. The arguments were previously considered and not found to be persuasive for the reasons of record.

Applicant reiterates arguments drawn to predictability of the claimed invention. The arguments were previously considered and not found to be persuasive for the reasons of record.

Applicant provides arguments drawn to an Affidavit by inventor Dr. Gail Clinton. However, neither the arguments nor the affidavit have been or will be considered because Applicant has not provided good and sufficient reasons why they were not previously presented.

Applicant reiterates almost verbatim the "Rebuttal to Examiner's Arguments set forth in the paper submitted May 3, 2006, pages 16-17. These arguments were previously considered but not found to be persuasive for the reasons of record.

Applicant reiterates arguments drawn to the findings of Rochester v. Searle and amplifies discussion of the issues set forth in Rochester v. Searle previously raised by Applicant. The issues remain the same and the arguments drawn to those issues were previously considered and despite the amplification of discussion are still not found to be persuasive for the reasons of record.

Applicant reiterates verbatim the section of the "Rebuttal to Examiner's Arguments drawn to "Public policy considerations" set forth in the paper submitted May 3, 2006, pages 17-18. Once again, Applicant's statement on public policy is noted.

2. Claims 18-20, 29-30 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the: paper mailed July 26, 2006, Section 5, pages 10-11.

Applicant reiterates, almost verbatim the section drawn to "Additional Rejection under 35 USC 112, first paragraph" at pages 18-20 except that Applicant points to Declarations previously considered that were not found to be persuasive. The issues remain the same, these arguments were previously considered but not found to be persuasive for the reasons of record.

3. Claims 8-10, 18, 29-30 remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the: paper mailed July 26, 2006, Section 6, page 11.

Applicant argues that the specification as originally filed describes a genus of compounds comprising SEQ ID NO:1 or 50-79 contiguous amino acid-containing fragments thereof and that bind at nanomolar concentrations, meaning that they would have a binding affinity of at least 108M-1. Applicant points to the specification at page 7, for example, in the legend of Figure 7, describes the use of nanomolar concentrations for binding. Further, Applicant points to the specification at page 8 that recites that "the unique ECD11a peptide binds with high affinity (nm concentrations)". Finally Applicant argues that the specification clearly teaches that SEQ ID NO:2 is also regarded as binding with an affinity of at least 108M-1 because it is used at nanomolar concentrations in the specification examples and as described above, SEQ ID NO:2 or any polypeptide comprising SEQ ID NO:2 or that comprises the C-terminal contiguous 79 amino acid residues thereof would also comprise SEQ ID NO:1 and thus would be encompassed within and thus defined by a genus of compounds that comprise SEQ ID NO:1 or 50-79 contiguous amino acid-containing fragments thereof.

The argument has been considered but has not been found persuasive because, at least as drawn to SEQ ID NO:2, Applicant is arguing limitations not recited in the claims as currently constituted. Further, nothing in Applicant's arguments is drawn to the claim limitation of an affinity binding constant of at least 108M-1 and for the reasons of record, nothing is found in the specification that suggests any support for this particular specific limitation or that this limitation was contemplated at the time the invention was made. The arguments have been considered but have not been found persuasive and the rejection is maintained.

4. Claims 8-10, 18, remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the: paper mailed July 26, 2006, Section 6, page 12.

Applicant argues page 5, line 23 and page 16 line 5 provide explicit literal support for this limitation wherein the specification describes "a consensus asparagine linked glycosylation site" and points out that those of skill recognize that "N-linked" and "asparagines linked" refer to the same amino acid because "N" is the single letter abbreviation for asparagines. Thus the specification teaches a single asparagines linked site at page 5, line 23 and page 16 line 5. Further the specification discloses that the ECD portion of herstatin contains five N-glycosylation sites and that the novel 79 amino acid portion contains one consensus N-linked glycosylation site.

The argument has been considered but has not been found persuasive because the disclosure of a consensus sequence, the disclosure that the claimed fragment contains one consensus N-linked glycosylation site, the disclosure that the ECD portion of herstatin contains five N-glycosylation sites does not provide support literal explicit support for the limitation drawn to "An isolated polypeptide comprising the amino acid sequence of SEQ ID NO:2, or a fragment of SEQ ID NO:2 of about 80 to 419 contiguous residues in length, wherein the C terminal 79 contiguous amino acids are present, wherein at least one N-linked glycosylation site is present". The

newly added limitation broadens the scope of the claimed invention. The arguments have been considered but have not been found persuasive and the rejection is maintained.

5. Claims 18 and 30, remain rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 26, 2006, Section 7, pages 12-13.

Applicant argues that there is explicit literal support for the newly claimed limitations at page 9, line 31 through page 10, line 9 and reiterates previous arguments drawn to pages 9-10. The arguments were previously considered but not found persuasive for the reasons of record.

6. Claim 9 remains rejected under 35 USC 112, first paragraph for the reasons previously set forth in the paper mailed July 26, 2006, Section 8, page 13.

- Because Applicant did not provide reasons why the instant rejection is improper, the rejection is maintained..

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